

Notice of Allowability	Application No.	Applicant(s)	
	10/758,025	HILDESHEIM ET AL.	
	Examiner	Art Unit	
	Janet L. Coppins	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to the telephone conversation of May 27, 2005 with Applicants' attorney.
2. ☒ The allowed claim(s) is/are 39-42 and 83.
3. ☒ The drawings filed on 16 January 2004 are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
 6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.
- Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).**
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

- | | |
|-----------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1. <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 5. <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 2. <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 6. <input type="checkbox"/> Interview Summary (PTO-413),
Paper No./Mail Date _____. |
| 3. <input checked="" type="checkbox"/> Information Disclosure Statements (PTO-1449 or PTO/SB/08),
Paper No./Mail Date <u>5/31/04</u> | 7. <input checked="" type="checkbox"/> Examiner's Amendment/Comment |
| 4. <input type="checkbox"/> Examiner's Comment Regarding Requirement for Deposit
of Biological Material | 8. <input checked="" type="checkbox"/> Examiner's Statement of Reasons for Allowance |
| | 9. <input type="checkbox"/> Other _____. |

S.O.O.

DETAILED ACTION

Claims 22-83 pending in the instant application.

Information Disclosure Statement

1. Receipt is acknowledged of Applicants' Information Disclosure Statement (IDS), filed May 3, 2004, which have been considered by the Examiner. Please refer to the copy of Applicants' PTO-1449 form submitted herewith.

Response to Amendment

2. Receipt is acknowledged of Applicants' Response, filed March 21, 2005, which has been reviewed by the Examiner and entered of record in the file.
3. Accordingly, claims 1-21 have been cancelled, claims 40 and 42 have been amended, and new claim 83 has been added.

Election/Restrictions

4. Applicant's election **without traverse** of Group VI, claims 39-42 and 83, drawn to carvedilol HCl hydrate and its crystalline forms, in the reply filed on March 21, 2005, is acknowledged.
5. This application is in condition for allowance except for the presence of claims 22-38, and 43-82, drawn to non-elected inventions.
6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

EXAMINER'S AMENDMENT

7. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Joseph A. Coppola on May 27, 2005.

The application has been amended as follows:

- (a) Please cancel claims 22-38 and 43-82.

Allowable Subject Matter

8. Claims 39-42 and 83, are allowable, as newly renumbered as claims 1, 3, 4, 5, and 2.

The following is an examiner's statement of reasons for allowance: This invention relates to a novel hydrate of carvedilol, carvedilol HCL hydrate, and its crystalline form. This application is a Divisional of U.S. Appl. No. 09/894,798, now U.S. Pat. No. 6,699,997 B2. The instant claimed compounds are found allowable because certain solvates of carvedilol and their crystalline forms are known to those skilled in the art as useful β -blocking and vasodilating agents. However the aspect of preparing a hydrate of carvedilol HCl, and its crystalline form, is novel and unobvious. The closest of prior art fails to teach or render obvious the preparation of the aforementioned compounds that contain the same carvedilol hydrate moiety. For example, Chen et al disclose the synthesis of a crystal of a solvate of carvedilol, however the journal does not teach the same hydrate of carvedilol as instantly claimed, or its crystalline form. Therefore,

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the prior art of record does not teach or fairly suggest the instant claimed compounds or their utility as vasodilating agents for treating hypertension, for example.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Coppins whose telephone number is 571.272.0680. The examiner can normally be reached on M-F 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571.272.0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Janet L. Coppins
May 302005

KAMAL A. SAEED, PH.D.
PRIMARY EXAMINER

for Kamal Saeed
Joseph K. McKane
SPE, Art Unit 1626